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| TRANSMITTAL FORM (to be used for all correspondence after initial form) | | U.S. Paten are required to respond to a collection Application Number Filing Date First Named Inventor Art Unit Examiner Name Attorney Docket Number | Approve t and Trademar | PTO/SB/21 (01-03) ed for use through 04/30/2003. OMB 0651-0031 k Office; U.S. DEPARTMENT OF COMMERCE n unless it displays a valid OMB control number. |
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| Fee Transmittal Form Fee Attached Amendment/Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 | | Prawing(s) icensing-related Papers Petition Petition to Convert to a Provisional Application Prower of Attorney, Revocation Phange of Correspondence Address Perminal Disclaimer Request for Refund Page 100 (20) | | After Allowance Communication to Group Appeal Communication to Board of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Other Enclosure(s) (please Identify below): |
| | TURE O | F APPLICANT, ATTORNI | EY, OR AG | ENT |
| Date November 10, 2004 | | ATE OF TRANSMISSION | /MAILING | |
| I hereby certify that this correspondence is being tra mail in an envelope addressed to: Commissioner fo Typed or printed Samuel H. Megerd | r Patents, P | the USPTO or deposited with the Un O. Box 1450, Alexandria, VA 2231 | ited States Pos 3 on this date | tal Service with sufficient postage as first class November 10, 2004 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Date November 10, 2004

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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIODNER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

EXAMINER

APPLICATION NO.

FIRST NAMED INVENTOR

ATTORNEY DOCKET NO.

CONFIRMATION NO.

10/616,359

Fred Thomas Bizzarro

20400 US6 -

1357

7590

06/23/2004

HOFFMANN-LA ROCHE INC. PATENT LAW DEPARTMENT 340 KINGSLAND STREET NUTLEY, NJ 07110

LAMBKIN, DEBORAH C ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

STATUTORY PERIOD EXPIRES:

PTO-90C (Rev. 10/03)

Copy Sent to Department PLP

| OIPE | | , |
|--|---|---|
| | Application No. | Applicant(s) |
| (NOV 1 2 2004) | 10/616,359 | BIZZARRO ET AL. |
| Office Action Symmary | Examiner | Art Unit |
| CA TRAINEMARK | Deborah C Lambkin | 1626 |
| เกษ ฟลาะเพอ อลาะ งา นี้แร communication app Period for Reply | Udars VII line Cuver Sheet Will line (| CGH copollucilos duulcoo |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply be till by within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE. | mely filed ys will be considered timely. In the mailing date of this communication. ED (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed on <u>08 N</u> | flarch 2004 | * |
| • | s action is non-final. | |
| 3) Since this application is in condition for allowa | | osecution as to the merits is |
| closed in accordance with the practice under the | • | • |
| • | | |
| Disposition of Claims | | 9 |
| 4)⊠ Claim(s) <u>1-278</u> is/are pending in the application | | |
| 4a) Of the above claim(s) 2-278 is/are withdraw | wn from consideration. | |
| 5) Claim(s) is/are allowed. | | |
| 6)⊠ Claim(s) <u>1</u> is/are rejected. | | |
| 7) Claim(s) is/are objected to. | * | |
| 8) Claim(s) are subject to restriction and/o | or election requirement. | |
| Application Papers | | |
| 9) The specification is objected to by the Examine | er. | |
| 10) The drawing(s) filed on is/are: a) acc | | Examiner. |
| Applicant may not request that any objection to the | | • |
| Replacement drawing sheet(s) including the correct | ••• | |
| 11) The oath or declaration is objected to by the E | | |
| | | |
| Priority under 35 U.S.C. § 119 | • | |
| 12) Acknowledgment is made of a claim for foreign | n priority under 35 U.S.C. § 119(a | a)-(d) or (f). |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | . 90 |
| 1. Certified copies of the priority document | | • |
| 2. Certified copies of the priority document | | |
| Copies of the certified copies of the price | ority documents have been received | ved in this National Stage |
| application from the International Burea | · | |
| * See the attached detailed Office action for a list | of the certified copies not receiv | red. |
| • | | DEBORAH C. LAMBKIN |
| | | PRIMARY |
| Attachment(s) | | * |
|) Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) Interview Summar Paper No(s)/Mail [| |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (P10-948) 3) ☑ Information Disclosure Statement(s) (PT0-1449 or PT0/SB/08) | | Patent Application (PTO-152) |
| Paper No(s)/Mail Date | 6) Other: | * * |
| 5. Patent and Trademark Office TOL-326 (Rev. 1-04) Office A | ction Summary | Part of Paper No./Mail Date 61704 |

Application/Control Number: 10/616,359

Art Unit: 1626

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 3/8/04 is acknowledged. The traversal is on the ground(s) that it is improper to restrict intraclaim. Although not agreeing with this entirely, the present restriction requirement is hereby withdrawn and the generic claim would be examined according to MPEP 803.02 for Markush-type claims, where there is an election of species involved.

As a result, only claim 1 would be examined to a reasonable extent necessary to determine allowability; hence claims 2-278 are being temporarily held withdrawn from further consideration pending the outcome of claim 1.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,320,050. This is a double patenting rejection.

Application/Control Number: 10/616,359

Art Unit: 1626

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C Lambkin whose telephone number is 571-272-0698.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.

DEBORAH C. LAMBKIN
PRIMARY EXAMINER

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|------------------|----------|--|--|---|---------------|------------------|-------------------|----------|--|--|--|
| ORM PTO-144 | 9 | U.S. Department of Patent and Tradema | Commerce rk Office | Atty. Docket No. 20400U | S6 Seria | 1 No. 10/616 | 5,359 | | | | |
| 7 | ORM. | ATION CLASED BY APP eral sheets if necessary) | LICANT | Applicants: Bizzaro, et al | | | | | | | |
| OCT 0 2 2004 2 | | | | 1'thing Date. 07/03/2003 | | | | | | | |
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| EXAMINER INITIAL | A | DOCUMENT | DATE | NAME | · | BOBOLASS | IF APPROPRIATE | | | | |
| Du | A1 | 3,431,301 | 3/4/69 | Focella et al. | · | | | | | | |
| me | A2 | 3,776,917 | 12/4/73 | Mann et al. | | | <u> </u> | | | | |
| m | A3 | 5,556,859 | 9/1996 | Johnson | | | | | | | |
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| ou | B1 | EP 566 138 | 10/20/93 | _ | | | YES | NO | | | |
| | B2 | WO 00/26202 | 5/11/00 | World (PCT) | | | | _ | | | |
| | В3 | 1,436,502 | 5/19/76 | Spain | | | | <u> </u> | | | |
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| | | OTHER ART (| Including A | uthor, Title, Date, Pertine | nt Pages, E | tc.) | · · · | | | | |
| Du | C1 | Rodier et al., Ac | eta Crystallo | gr., C46, pg. 154-156 (19 | 190) | . <u> </u> | | | | | |
| pu | C2 | Robert et al., Et | Robert et al., Eur. J. Med. Chem., Vol. 29, pgs. 841-854 (1994) | | | | | | | | |
| | C3 | 1 | Spickett et al., Eur. J. Med. Chem. –Chimica Therapeutica, Vol. 11(1), pgs. 7-12 (1976) Bhat et al., Inst. Chemists (India), Vol. 61, pgs. 134-136 (1989) | | | | | | | | |
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| V | C5 | Spielman, M.A | ., et. al. J. A | m. Chem. Soc., 70, pp. 4 | 189-4191 (| 1740) | · . | <u>.</u> | | | |
| 7 | 1 | | | | | | | | | | |
| EXAMINER | <i>y</i> | D. Lambher. | | DATE CONSIDERED | φ | 7/04 | on if not in | | | | |
| *EXAMINER | Initial | if reference considered, whe onsidered. Include copy of t | ther or not citat his form with no | ion is in conformance with MPEP ext communication to applicant. | UU7, DIAW III | io unough viculi | | | | | |